

**REMARKS**

Claims 1, 7, 11, 13, 14, 17, 18, 20, 21, 24, 25, 28, 29, 33, 34, and 35 are pending. Claims 25, 28, 29, 34, and 35 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1 and 20 are currently amended. Claim 1 is amended to remove non-elected subject matter. Support for the amendments to claims 1 and 20 may be found, for example, at page 17, lines 5-21 and page 21, lines 5-8. Applicant reserves the right to prosecute the non-elected subject matter in a continuing application.

Reconsideration of the application is requested.

**§ 112 Rejections**

Claims 1 and 20 are rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The terms "aryl", "heteroaryl", and "heterocyclyl" are said to be indefinite because the specification allegedly does not define the ring size, heteroatom, number and nature of substituents, and the exact point of contact with the substituent.

However, the specification, for example, at page 17, lines 5-21 provides a number of examples for each of these terms, thereby providing the skilled person with sufficient description to understand the meaning of these terms. However, in the interest of progressing the application, claims 1 and 20 have been amended to include this description.

Accordingly, Applicant respectfully requests that the rejection under 35 USC § 112, second paragraph, be withdrawn.

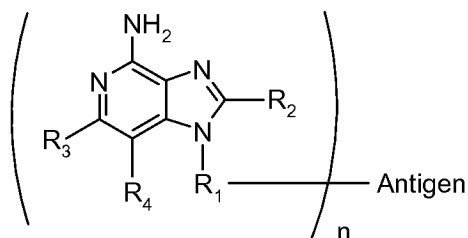
**§ 102 Rejections**

Claims 1, 7, 11, 13, 14, 17, 18, 20, 21, 24, and 33 are rejected under 35 USC § 102(e) as being anticipated by U.S. Patent No. 7,427,629 (Kedl et al.).

Applicant traverses this rejection.

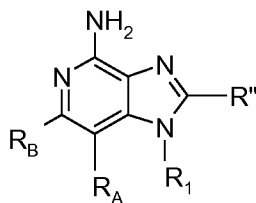
Kedl et al. discloses that IRMs, especially small molecule IRMs and agonists of TLR 2, 4, 6, 7, and 8, are surprisingly effective at stimulating an immune response when chemically or physically paired with an antigen to form an immunostimulatory composition. (See column 2, lines 16-20). Kedl et al. disclose a Reaction Scheme I, which includes the immune response conjugate

of Formula I, wherein an antigen-containing moiety is linked to the IRM moiety through  $R_1$ . (See column 7, line 46 through column 8, line 64.)



I

The present claims are directed to a compound of Formula I or a pharmaceutically acceptable salt thereof



I

wherein  $R_1$  is defined as follows:

$R_1$  has the formula alkylene-L- $R_{1-1}$ , alkenylene-L- $R_{1-1}$ , or alkynylene-L- $R_{1-1}$ , wherein:

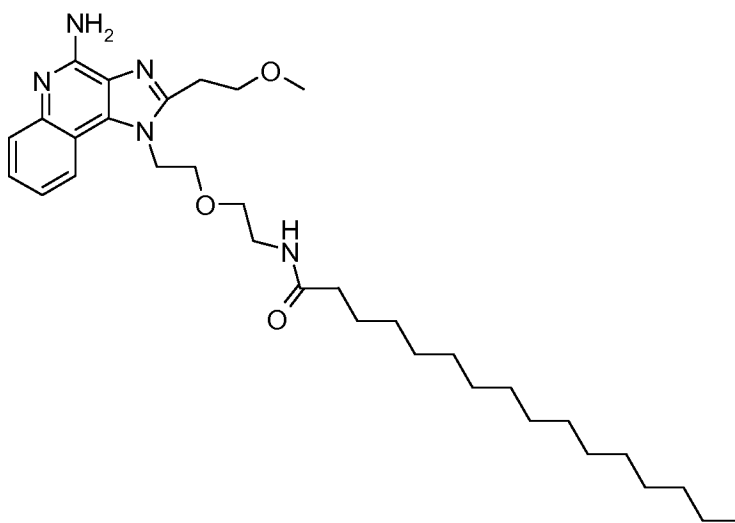
the alkylene, alkenylene, and alkynylene groups are optionally interrupted with one or more -O- groups;

L is a bond or a functional linking group selected from the group consisting of -NH-S(O)<sub>2</sub>-, -NH-C(O)-, -NH-C(S)-, -NH-S(O)<sub>2</sub>-NR<sub>3</sub>-, -NH-C(O)-NR<sub>3</sub>-, -NH-C(S)-NR<sub>3</sub>-, -NH-C(O)-O-, -O-, -S-, and -S(O)<sub>2</sub>-; and

$R_{1-1}$  is a linear or branched aliphatic group having at least 11 carbon atoms, optionally including one or more unsaturated carbon-carbon bonds.

Referring to columns 8-10 and 17 of Kedl et al., the Office Action alleges that the compounds of Kedl et al. have the same structure as the presently claimed compounds. However, columns 8-10 provide no teaching or suggestion of  $R_1$  as defined in the presently claimed compound which includes an  $R_{1-1}$  group which is a linear or branched aliphatic group having at least 11 carbon atoms, optionally including one or more unsaturated carbon-carbon bonds.

The Office Action also refers to column 17 in Kedl et al., which includes a preparation of IRM Compound 3: *N*-(2-{2-[4-amino-2-(2-methoxyethyl)-1*H*-imidazo[4,5-*c*]quinolin-1-yl]ethoxy}ethyl)hexadecanamide



This compound does indeed fall within the scope of the present claims. However, the present application claims priority to this disclosure which was filed as U.S. Patent Application Serial No. 10/640,904 on August 14, 2003 (now U.S. Patent No. 7,427,629 (Kedl et al.)).

It is noted that Kedl et al. claims priority to U.S. Provisional Patent Application Serial No. 60/403,846, filed August 15, 2002. However, IRM Compound 3 was not disclosed in this prior provisional application. Therefore, Kedl et al. is disqualified as prior art with respect to its disclosure of IRM Compound 3.

For at least these reasons, Kedl et al. does not anticipate the present claims under 35 USC § 102(e), and Applicant respectfully requests that this rejection be withdrawn.

Claims 1, 7, 11, 13, 14, 17, 18, 20, 21, 24, and 33 are also rejected under 35 USC § 102(e) as being anticipated by U.S. Patent No. 7,091,214 (Hays et al.).

Applicant traverses this rejection.

Hays et al. discloses a class of compounds which have a substituent comprising an aryl, arylene, heteroaryl, or heteroarylene group at the 6, 7, 8, and/or 9 position of an imidazoquinoline ring system.

The present claims are directed to a compound Formula I or pharmaceutically acceptable salt thereof as noted above, where the 6, 7, 8, and 9 positions, when present, are unsubstituted or substituted by one or more R groups; where each R is independently selected from the group consisting of

halogen,  
hydroxy,  
alkyl,  
alkenyl,  
haloalkyl,  
alkoxy,  
alkylthio, and  
-N(R<sub>3</sub>)<sub>2</sub>.

No aryl, arylene, heteroaryl, or heteroarylene containing substituent is included as the R group in the presently claimed compounds.

In support of the rejection, the Office Action referred to Examples 1-14 of Hays et al. It is noted, however, that upon reviewing the specific Examples 1-1020 disclosed in Hays et al., no R<sub>1</sub> group as specified in the present claims is found.

For at least these reasons, Hays et al. does not anticipate the present claims under 35 USC § 102(e), and Applicant respectfully requests that this rejection be withdrawn.

### **§ 103 Rejections**

Claims 1, 7, 11, 13, 14, 17, 18, 20, 21, 24, and 33 are rejected under 35 USC § 103(a) as being unpatentable over Kedl et al.

Applicant traverses this rejection.

As noted above, that portion of Kedl et al. which has a priority date earlier than the present application provides no teaching or suggestion to arrive at the presently claimed compounds. No R<sub>1</sub> group as specified by the present claims is found in that portion of Kedl et al. Instead, an antigen is linked to an IRM through an R<sub>1</sub> group. Without the benefit of the present application, no reason or motivation is provided by that portion of Kedl et al. for the person of ordinary skill in the art to modify the compounds disclosed therein to arrive at the R<sub>1</sub> group as specified by the present claims.

For at least these reasons, a prima facie case of obviousness is not established, and Applicant respectfully requests that the rejection under 35 USC § 103(a) as being unpatentable over Kedl et al. be withdrawn.

Claims 1, 7, 11, 13, 14, 17, 18, 20, 21, 24, and 33 are also rejected under 35 USC § 103(a) as being unpatentable over Hays et al.

Applicant traverses this rejection.

As noted above, Hays et al. discloses a class of compounds which have a substituent comprising an aryl, arylene, heteroaryl, or heteroarylene group at the 6, 7, 8, and/or 9 position of an imidazoquinoline ring system. The person of ordinary skill has no reason or motivation to remove this substituent to arrive at the presently claimed compounds. In fact, doing so would destroy the very reason for the existence of Hays et al. Moreover, even if such a modification were made, the person of ordinary skill would still need to select the R<sub>1</sub> groups required in the presently claimed compounds, from a large genus of possible R<sub>1</sub> groups in Hays et al. No direction is provided in Hays et al. for such a selection. No Examples are provided in Hays et al. with such an R<sub>1</sub> group.

For at least these reasons, a prima facie case of obviousness is not established, and Applicant respectfully requests that the rejection under 35 USC § 103(a) as being unpatentable over Hays et al. be withdrawn.

### **Request for Rejoinder**

Withdrawn claims 25, 28, 29, 34, and 35 incorporate all the claim features of currently amended patentable claims 1 and 20. Accordingly, it is submitted that they are likewise patentable. Rejoinder of these claims is respectfully requested.

### **Conclusion**

Applicant also notes that there may be other arguments which were not presented herein, and Applicant does not concede those arguments by not having presented them herein. Applicant also does not necessarily agree with the correctness of statements made in the Office Action that were not rebutted herein, if any such instances are present.

In view of the foregoing amendments, Applicant respectfully requests examination and reconsideration of the application and allowance of the claims as all rejections have been overcome. Early notice of allowance is kindly requested.

The Examiner is invited to contact the undersigned by telephone at 651-733-7830 with any questions or comments.

Respectfully submitted,

13 May 2009

Date

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